

REMARKS

I. The Amendments

Following entry of this Amendment, claims 1-10 and 12-20 are pending in this application. Claim 11 has been canceled. Claims 1, 9, 12 and 16 were amended for clarification and are supported in the specification. Examples of such support are as follows: claim 1: page 9, lines 16-20; page 17, lines 2-4; claim 9: page 17, lines 2-4; claim 12: page 9, line 31; claim 16: page 9, lines 16-20; page 17, lines 2-4. No new matter has been added. Applicant respectfully submits that claims 1-10 and 12-20 are in condition for immediate allowance. Applicant addresses the Examiner's rejections in the order they were presented in the Office Action.

II. 35 U.S.C. §112, second paragraph

Claims 9 and 16-20 were rejected under 35 U.S.C. § 112, second paragraph, for allegedly being indefinite. According to the Examiner, claims 9 and 16-20 are allegedly indefinite for reciting the term "a nutrient-poor environment found on the skin".

Applicant respectfully submits that the rejection is moot.

Applicant respectfully requests withdrawal of this rejection.

III. 35 U.S.C. §112, first paragraph

Claims 1-20 were rejected under 35 U.S.C. § 112, first paragraph, for being non-enabling. According to the Examiner, claims 1-20 are allegedly not commensurate with the enabling disclosure to a skilled artisan. Applicant respectfully submits that the rejection is moot

Applicant respectfully requests withdrawal of this rejection.

IV. 35 U.S.C. §102

a. Claims 1-12 and 14-20 were rejected under 35 U.S.C. § 102(b) as allegedly anticipated by United States Patent No. 6,117,676 to Sakuragawa ("Sakuragawa"), and the Examiner alleges that such anticipation is evidenced by Uchida *et al.*, 2000, J. Neurosci. Res. 62:585-590 ("Uchida"). Applicant respectfully traverses the rejection.

Applicant submits that Sakuragawa does not teach or suggest each and element whereby to put those in the art in possession of the invention. For example, Sakuragawa does not teach or suggest "[a] method for delivering a molecule to the skin of a patient comprising administering amniotic epithelial cells to the skin of the patient; wherein said cells are capable of delivering said molecule, are genetically modified to deliver said molecule, are part of a reconstituted tissue membrane, and are topically applied to said skin", as described in the claims. Sakuragawa discusses gene therapy that involves the transplantation of "amniotic cells" into the patient (*e.g.*, column 3, lines 51-59) and that the cells are transplanted "subcutaneously" (*e.g.*, column 4, lines 2-3). Sakuragawa can therefore not anticipate (or obviate) the subject invention as it does not teach or suggest each and every element described in the claims. Applicant submits that Uchida does not cure the deficiencies of Sakuragawa and the Examiner has not shown otherwise.

Applicant therefore respectfully requests withdrawal of this rejection.

b. Claims 1-5, 7-13, 16-18 and 20 were rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Faulk *et al.*, 1980, Lancet 1(8179):1156-1158 ("Faulk"), and the Examiner alleges that such anticipation is evidenced by Uchida. Applicant respectfully traverses the rejection.

Applicant submits that Faulk does not teach or suggest each and element whereby to put those in the art in possession of the invention. For example, Faulk does not teach or suggest "[a] method for delivering a molecule to the skin of a patient comprising administering amniotic epithelial cells to the skin of the patient; wherein said cells are capable of delivering said molecule, are genetically modified to deliver said molecule, are part of a reconstituted tissue membrane, and are topically applied to said skin", as described in the claims. The Examiner alleges that "[i]nasmuch as the cells of Faulk are composed of molecules, Faulk teaches the delivery of molecules to a patient." Yet, the cells described in the subject claims "are capable of delivering said molecule," which is inconsistent with the Examiner's allegation. Applicant submits that Uchida does not cure the deficiencies of Sakuragawa and the Examiner has not shown otherwise.

Applicant therefore respectfully requests withdrawal of this rejection.

c. Claims 16-19 were rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Eming *et al.*, 1996, Biotech. Bioeng. 52(1):15-23 ("Eming"). Applicant respectfully traverses the rejection.

Applicant respectfully submits that Eming discusses the use of cells "inserted under a full-thickness skin flap" (page 17, left column). Eming does not teach or suggest "[a] method for delivering a molecule to the skin of a patient comprising administering amniotic epithelial cells to the skin of the patient; wherein said cells are capable of delivering said molecule, are genetically modified to deliver said molecule, are part of a reconstituted tissue membrane, and are topically applied to said skin", as described in the claims.

Applicant therefore respectfully requests withdrawal of this rejection.

V. 35 U.S.C. §103

a. Claims 1-6 and 14-19 were rejected under 35 U.S.C. § 103(a) as allegedly obvious over Faulk in view of Eming and Sakuragawa. Applicant respectfully traverses the rejection.

Applicant discussed above the deficiencies of the primary reference Faulk cited by the Examiner, and Applicant also discussed the deficiencies of Eming and Sakuragawa, and Eming and Sakuragawa therefore do not cure the deficiencies of Faulk.

Applicant further notes that the Examiner has not made the requisite showing of a suggestion to combine references with a reasonable expectation of success. ("Where claimed subject matter has been rejected as obvious in view of a combination of prior art references, a proper analysis under § 103 requires, *inter alia*, consideration of two factors: (1) whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition or device, or carry out the claimed process; and (2) whether the prior art would also have revealed that in so making or carrying out, those of ordinary skill would have a reasonable expectation of success. ... Both the suggestion and the reasonable expectation of success must be

founded in the prior art, not in the applicant's disclosure." *In re Vaeck*, 947 F.2d 488, 493 (Fed. Cir. 1991) (citations omitted).)

Applicant respectfully submits that the Examiner has not made the requisite showing for combining the references with a reasonable expectation of success of record. "When patentability turns on the question of obviousness, the search for and analysis of the prior art includes evidence relevant to the finding of whether there is a teaching, motivation, or suggestion to select and combine the references relied on as evidence of obviousness. ... 'The factual inquiry whether to combine references must be thorough and searching.' ... It must be based on objective evidence of record." *In re Sang-Su Lee*, 277 F.3d 1338, 1343, 61 U.S.P.Q.2d 1430 (Fed. Cir. 2002) (citations omitted). It has also been held that "the suggestion to combine requirement stands as a critical safeguard against hindsight analysis and rote application of the legal test for obviousness." *In re Rouffet*, 149 F.3d 1350, 1358, 47 U.S.P.Q.2d 1453 (Fed. Cir. 1998). Therefore, "a rejection cannot be predicated on the mere identification in [the references] of individual components of claimed limitations. Rather, particular findings must be made as to the reason the skilled artisan, with no knowledge of the claimed invention, would have selected these components for combination in the manner claimed." *In re Kotzab*, 217 F.3d 1365, 1371, 55 U.S.P.Q.2d 1313 (Fed. Cir. 2000).

Applicant submits that, in addition to the references' deficient teachings, there is no suggestion to combine the references and no evidence supporting such a combination has been made of record, nor has a reasonable expectation of success been shown. Applicant respectfully submits that the Examiner's reference to "the expectation of some advantage" is deficient because it relies upon picking and choosing references and further picking and choosing elements from those references while impermissibly using the subject invention as a blueprint. Also, the elements of the subject invention are not found in the cited references.

Applicant therefore respectfully requests withdrawal of this rejection.

b. Claims 1-6 and 14-19 were rejected under 35 U.S.C. § 103(a) as allegedly obvious over Faulk in view of Eming, Sakuragawa and United States Patent Number 6,191,269 to Pollock *et al.* ("Pollock"). Applicant respectfully traverses the rejection.

Applicant discussed above the deficiencies of Faulk, Eming and Sakuragawa, and Pollock does not cure the deficiencies of these references and the Examiner does not allege otherwise. Also, no proper evidence of any suggestion to combine any or all of these references has been made of record and Applicant respectfully requests same.

Applicant therefore respectfully requests withdrawal of this rejection.

VI. Conclusion

Applicant respectfully submits that pending claims 1-10 and 12-20 are in condition for immediate allowance. The undersigned invites the Examiner to call (650) 838-4382 with any questions or comments. The Commissioner is hereby authorized and requested to charge any deficiency in fees herein to Deposit Account No. 50-2207.

Respectfully submitted,
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Date: May 23, 2005

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